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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,343	07/08/2003	Xiao-Jia Chang	IGA-003.01	8723

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EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/615,343	CHANG, XIAO-JIA	
	Examiner	Art Unit	
	James L. Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-75* is/are pending in the application.

4a) Of the above claim(s) *16-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-75* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/5/05;10/19/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election with traverse of Group I, claims 1-15, in the communication filed 03 April 2006 is acknowledged. The traversal is on the ground(s) that the characteristics required by claim 1 of Group I are required for Group VI, that the Groups are therefore related as subcombination and combination, and that searching Groups I and VI together would not be burdensome. This is not found persuasive because the overlapping subject matter of claim 1 was included, not excluded, in Group VI, the different inventions of the otherwise different groups remain patentably distinct for the reasons of record, and the searches required for the different inventions are clearly not co-extensive and, as such, are evidence of a burden. Accordingly, claims 16-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no (allowable) generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

The disclosure is objected to because of the following informalities: the imbedded active hyperlinks on page 28 are an impermissible incorporation by reference of the information on the referenced web page and deletion of elements which make them active, including deletion of "http://", and/or underlining, is required. Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and claims dependent thereupon, the interrelationships of the steps and components of the method are not clear, e.g. it is not clear what is being determined because fusion protein comprising carrier protein is contacted with antibodies and is present and, thus, it is not clear in or on what the presence of the carrier protein is being determined. Moreover, in these claims, "the presence" lacks antecedent basis.

In claim 3, it is not clear what is within the metes and bounds of "associated with a disease" and intended as encompassed.

Claims 12-15 are method claims and, as such, they should clearly set forth the various method steps in a positive, sequential manner using active tense verbs such as mixing, reacting, and detecting. "Using" or a variation thereof such as "employing" or "used" is not a valid method step.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent,
except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language;

Claims 1-3, 10, 14, and 15 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Kramer et al. (US 5,217,896).

Kramer et al. screened hybridoma supernatants for antibodies specific for parathyroid hormone-like protein with antigen capture assays (see e.g. cols. 13-14, 18). Wells were coated with hybridoma supernatants to bind the antibodies to the surface, a fusion protein was added to the coated wells, unbound fusion protein washed off, and the bound fusion protein was detected with a fusion protein specific antibody. Alternatively, immunoprecipitations were done to detect antibody antigen complexes.

Claims 1-3, 9, and 15 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Goodwin et al. (US 6,143,869).

Goodwin et al. screened hybridoma supernatants for antibodies specific for human CD30 with an antigen capture assay (see e.g. cols. 33-34). Wells were coated with hybridoma supernatants to bind the antibodies to the surface, a fusion protein was added to the coated wells, unbound fusion protein washed off, and the fusion protein bound to the surface was detected.

Claims 1-3, 10, and 15 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Martegani et al. (Am. J. Pathol. 154: 291, 1999).

Martegani et al. coated protein A sepharose beads with different antibodies, fusion proteins were added to the coated beads, unbound fusion proteins washed off, and the fusion proteins bound to the surface were detected (see e.g. page 294, col. 2).

Claims 1-3, 5, 9, and 15 are rejected under 35 U.S.C. § 102(e)(2) as being clearly anticipated by Thorpe et al. (US 6,703,020 B1).

Thorpe et al. coated wells with control or test antibodies to bind the antibodies to the surface, a fusion protein was added to the coated wells, including SEAP or Fc fusion proteins, unbound fusion protein washed off, and the bound fusion protein was detected with, among other means, a fusion protein specific antibody (see e.g. cols. 132 and 139).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ashkenazi et al. (US 6,252,050) combined with the teachings of Goodwin et al. (US 6,143,869), Thorpe et al. (US 6,703,020 B1), and Leder et al. (US 5,554,499).

Ashkenazi et al. performed immunizations with mixed fusion proteins (see e.g. cols. 13-14 and 27) to elicit antibodies, polyclonal and/or monoclonal, to the plurality of antigens contained in the mixture. A variety of antigens are suggested for use (cols. 12-14). Hybridoma supernatants were screened for monoclonal antibodies specific for the different antigens with a number of assays including antigen capture assays in which the antibodies in the supernatants are bound to a surface either before or after, such as in immunoprecipitation, reaction with labeled

antigen (see e.g. col. 16). In contrast to the invention as instantly claimed, the reference does not specifically teach the use of the fusion proteins in antigen capture screening assays.

The teachings of Goodwin et al. or Thorpe et al. are as set forth previously in this Office action.

Leder et al. teach cloning of fusion proteins, comprising a receptor and a member of a binding pair, in the secretory alkaline phosphatase-encoding APtag vector and detection of the proteins by enzymatic assays or immunoassays (see e.g. cols. 1-2). Although the reference teaches that the definitions of ligand and receptor, in the context of their invention of ligand isolation, do not include antigens and antibodies (see col. 3), the use of fusion proteins for immunizations and determinations of antigen-antibody reactions is clearly taught in the art, such as in any of Ashkenazi et al., Goodwin et al., or Thorpe et al.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have used fusion proteins in the antigen capture screening assays of Ashkenazi et al. because this is notoriously well-known in the art as taught in, among others, Goodwin et al. or Thorpe et al. It would have been further obvious to have used any available conventional fusion protein expression vector, such as the Aptag vector of Leder et al., for cloning the relevant antigens of Ashkenazi et al., as modified, motivated by the suggestion in Ashkenazi et al. to use heterologous fusion proteins, generally, with antigen fragments of interest and by the convenience of selecting from known and available vectors. Detection of the fusion protein in the assays of Ashkenazi et al., as modified, by well-known and conventional labeling means, such as by direct labeling (Ashkenazi et al.) with any conventional label, by direct or indirect anti-fusion protein antibody labeling (Leder et al., Goodwin et al., or Thorpe et al.) with

any conventional label, or with substrate for an enzymatic fusion protein (Leder et al.), would have been an obvious matter of design choice motivated by availability of detection reagents or apparatus, or by preference.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Beckmann et al. (J. Immunol. 144: 4212, 1990) teach capture screening methods for monoclonal antibody selection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 3, 2006

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05/03/06